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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,907	03/09/2004	Duran Yetkinler	SKEL-012CIP	3390
24353	7590	09/08/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,907

Applicant(s)

YETKINLER ET AL.

Examiner

Anu Ramana

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,22,24-27,29,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20,22,24-27,29,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 22, 24, 25, 27, 29, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bakels et al. (US 4,787,751).

Bakels et al. disclose a bone cement mixing device including a cement handling element 182 and a vibratory element 10 for vibrating cement during its preparation (Figs. 2 and 7, col. 2, lines 30-68 and col. 3, lines 1-62).

Claims 20, 22, 24, 25, 27, 29 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito (US 6,340,299).

Saito discloses a system for delivering a cement including a delivery device or cannula or needle 35, a vibration generating mechanism or "vibratory element" 11 for vibrating the cement delivery device and a cement composition (Fig. 2, col. 5, lines 11-67, col. 6, lines 37-45 and col. 7, lines 18-39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bakels et al. (US 4,787,751) in view of Genge et al. (US 6,808,561).

Art Unit: 3732

Bakels et al. disclose all elements of the claimed invention except for the bone cement being a calcium phosphate composition.

Genge et al. teach calcium phosphate bone cement for skeletal repair (col. 1, lines 27-40, col. 2, lines 42-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the Bakels et al. device for preparing a calcium phosphate cement.

Claims 1-3 and 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) in view of Bakels et al. (US 4,787,751).

Constantz et al. disclose a method of introducing a two component calcium phosphate cement for orthopedic applications utilizing a cement delivery means such as a needle wherein the needle is vibrated to enhance infiltration of cement (col. 25, lines 38-59, col. 27, lines 11-57, col. 28, lines 49-67 and col. 29, lines 1-67). Further, Constantz et al. utilize vibration to enhance cement infiltration. Thus, when vibration is stopped, infiltration of cement would "substantially stop."

Constantz et al. disclose all elements of the claimed invention except for combining the precursors of the cement with vibration.

Bakels et al. teach the use of mixing bone cement utilizing vibration to reduce porosity (col. 1, lines 5-8, col. 2, lines 30-68 and col. 3, lines 1-62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized vibration, as taught by Bakels et al., to mix the bone cement components of Constantz et al., to reduce its porosity prior to delivering the bone cement.

Regarding claim 6, the combination of Constantz et al. and Bakels discloses the claimed invention except for the claimed vibration frequency range. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have vibrated the bone cement at a frequency of about 0.1 to about 100,000 Hz, since it has been held that where the general conditions of a claim are disclosed in the prior art,

Art Unit: 3732

discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

The method steps of claims 1-3 and 5-19 are rendered obvious by the above discussion.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) and Bakels (US 4,787,751), as applied to claim 1, in view of Sproul (US 6,832,988).

Constantz et al. disclose all elements of the claimed invention except for the step of vibration in conjunction with preparation of a target bone site for introduction of cement.

Sproul teaches utilizing ultrasonic vibrations for maceration of diseased tissue prior to cement injection (col. 1, lines 29-38 and col. 7, lines 15-47).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized ultrasonic vibrations, as taught by Sproul, for removing diseased tissue during vertebroplasty according to the method of the combination of Constantz et al. and Sproul.

The method steps of claim 4 are rendered obvious by the above discussion.

Response to Arguments

Applicants' arguments filed on June 24, 2005 with respect to claims 1-20, 22, 24-27, 29, 31 and 32 have been fully considered.

Applicants' arguments with respect to the rejection of claims 20, 22, 24, 25, 27, 29, 31 and 32 as being anticipated by Saito (US 6,340,299) are not persuasive because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Art Unit: 3732

Applicants' arguments with respect to claims 1-19 are moot in view of the new grounds of rejection.

The Terminal Disclaimers filed on June 24, 2005 have overcome the double patenting rejections made in the previous office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

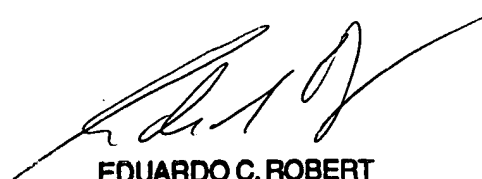
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Amundla Ramas*
September 6, 2005



EDUARDO C. ROBERT
PRIMARY EXAMINER